THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte ROBERT W. LANGLEY and LARRY J. DUMONT

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Appeal No. 1995-3522
Application No. 07/912,973[1]

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ON BRIEF

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Before KIMLIN, OWENS and KRATZ, Administrative Patent Judges.

KRATZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 13 through 15, which are all of the claims pending in this application.

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[1] Application for patent filed July 10, 1992.

BACKGROUND

The appellants' invention relates to an apparatus for providing a blood component product. According to appellants, the blood component yield, such as the number of platelets, must be determined with respect to a particular collection and associated therewith to obtain a useful blood component product (brief, page 4). An understanding of the invention can be derived from a reading of exemplary claim 13 which is reproduced below.

13. A system for providing a blood component product having a determined yield pursuant to at least one on-line yield determination technique, comprising:

means for harvesting a plurality of a predetermined type of a blood component from a source of blood;

first means for providing a first set of predetermined information relating to said source of blood;

second means for providing a second set of predetermined information relating to said means for harvesting;

third means for generating a predicted yield value based upon said first and second sets of predetermined information, said third means comprising said at least one on-line yield determination technique;

fourth means for providing a first calibration factor based upon said third means in relation to a predetermined off-line yield determination technique, said predetermined off-line yield determination technique allowing for

determining an off-line measured yield value of said harvested blood components;

fifth means for generating said determined yield, said fifth means utilizing at least in part an application of said first calibration factor to said predicted yield value; and

sixth means for packaging said harvested blood components and associating said determined yield therewith to provide said blood component product.

REJECTION

Claims 13-15 stand rejected under 35 U.S.C. § 112, first paragraph, on the ground that the specification is non-enabling.

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with the appellants that the aforementioned rejection is not well founded. In our view, the examiner has failed to carry his initial burden of establishing a prima facie case of non-enablement based on the present record. Accordingly, the above-noted rejection cannot be sustained.

The examiner attacks the sufficiency of appellants' specification urging, for example, that the specification does not adequately describe "how the predetermined information is used in the on-line yield determination technique to obtain a predicted yield" (answer, page 4); and the claims do not specify the type of information selected with regard to the claim 13 limitation of a "first means for providing a first set of predetermined information..." (answer, page 4). Moreover, the examiner challenges the adequacy of the disclosure asserting that the specification does not explain how to use the mathematical equations disclosed therein for obtaining a yield determination (answer, page 5). According to the examiner, the disclosure leaves many unanswered questions regarding the claimed apparatus. Appellants argue that an enabling disclosure of the claimed system for providing a blood component product within the meaning of 35 U.S.C. § 112, first paragraph, has been furnished (brief, pages 13-32), that the examiner appears to be requiring that the "claims themselves must be enabling" (reply brief, page 2) and that the examiner's reasoning and conclusions regarding

the specification teachings and support for the claimed subject matter are in error (reply brief, pages 2-13).

With respect to enablement, the predecessor of our appellate reviewing court stated in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971):

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . .
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> . . . .
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> . . . it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

In addition, an analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether one skilled in the art could make and use the claimed invention from the disclosure coupled with

information known in the art without undue experimentation. See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 109 S.Ct. 1954 (1989); In re Stephens, 529 F.2d 1343, 1345, 188 USPQ 659, 661 (CCPA 1976).

Here, even if we agreed with all of the examiner's criticisms of the specification (which we do not for reasons as generally presented in the appellants' brief and reply brief), the examiner's analysis would fall short of presenting a *prima facie* case of a non-enabling disclosure since the examiner did not supply any convincing evidence or reasoning which would cause
doubt about the accuracy of appellants' disclosure so as to support a legal conclusion that undue experimentation is required to practice the invention as claimed. See In re Wands, 858 F.2d 731, 736-37, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Moreover, we observe that the examiner has not convincingly explained how the criticisms and questions regarding the specification that the examiner has set forth in

the answer would support the notion that undue experimentation would have been required to practice the invention claimed herein. Indeed, we agree with appellants (brief, pages 13-32 and reply brief, pages 2-13) that the examiner has not even fairly represented the teachings of the specification regarding the claimed system for providing a blood component product.

Accordingly, in our view, the examiner has not carried his initial burden of setting forth evidence or sound technical reasoning which indicates that any person skilled in the art would not have been enabled by appellants' specification to construct the claimed apparatus and carry out the claimed invention according to the guidelines in appellants' specification.

For the above reasons, we do not sustain the rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

To summarize, the decision of the examiner to reject claims 13-15 under 35 U.S.C. § 112, first paragraph on the ground that the specification is non-enabling is reversed.

REVERSED

EDWARD C. KIMLIN Administrative Patent Judge	)
TERRY J. OWENS Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
PETER F. KRATZ Administrative Patent Judge	)

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